

SPL Process Team

July 25, 2012

Minutes

Chair: Mary Beth Wilusz

1. **NDC numbers on different layers of packaging – multiple units of sale within a larger carton.**
(Hospira –Kathy Lin)

Background information:

- Sponsor received feedback from FDA regarding the NDC code designation on the trade and inner unit of sale which resulted in SPL not being posted to DailyMed. They had been using a process for a number of years of assigning the trade NDC code (on the outer carton) for the inner package containing a single unit of use; and it had never been questioned before.
- During follow-up communications with the SPL Project Team, DRLS, and the review division, they received additional feedback that that correct process was to assign different NDCs to the inner unit of sale and the outer trade carton. Sponsor was also directed to the "File Notes" at the following link for more information:
<http://www.fda.gov/Drugs/InformationOnDrugs/ucm254528.htm>
- To be discussed: Changing the current practice will require significant amount of work (and time). The sponsor would like to learn what other pharma were doing and if anyone was also having this issue.

Example: In the example below, the same NDC is printed on both the outer carton and the inner single unit of use.

Packaging		
#	Item Code	Package Description
1	NDC: 1234-5678-04	10 VIAL, SINGLE-DOSE in 1 CARTON
1		4 mL in 1 VIAL, SINGLE-DOSE

Meeting Discussion:

- a. The discussion identified two other companies were assigning NDC codes based on the same processes – ie the same NDC code for both the single unit of use and the multipack carton/package.
 - i. Their interpretation of 21CFR 207.35. These companies use the same NDC code on both because the outer carton is the only trade presentation that is sold by the company.
- b. Steve Bass commented that industry received feedback 10 +years ago that different NDCs were needed on the different levels of packaging to provide clarity in product identification.

- i. Several companies responded saying that they had either always assigned NDCs in this manner or had switched to the process outlined by FDA.
 - ii. One company stated that she had issues with product reimbursement when the same NDC codes were assigned to both inner unit of use and the trade package. They differentiate the NDC codes and hadn't had any problem since then.
- c. Question arose about whether outer packaging needed NDC codes: ie either the outer shipping case label or when multiple cartons are shrink wrapped
 - i. Response: no. These are needed only for transport between the company and the distribution chain and are not regulated by FDA.
- d. What prompted this feedback now – since the NDC codes had not been questioned in the past.
 - i. Speculation: This could have been initiated by CMS. CMS has recently sent (Sept 2011 and May 14, 2012) letters informing Plan D Sponsors that CMS will use the FDA's Comprehensive NDC SPL Data Elements file (NSDE) to edit PDE (Prescription drug events).
 - ii. The letters included the notification, process, and instructions related to their use of information in the SPL drug listing files
 - iii. CMS will implement this new process will be implemented Sept 1, 2012. As of September 1st (with the NDDE file downloaded on August 15), any reimbursable unit must be drug listed in R4 directory in order to be reimbursable.
 - iv. NSDE file is located on the SPL resource page – SPL –Downloadable Data:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>
 - v. This letter was sent to Plan D sponsors, not manufacturers. In the letters, sponsors were instructed to contact manufacturers and/or FDA if any of the information in the SPL NSDE file was not correct.
 - vi. Pat and Mary Beth will send out a copy of this letter to all team members (sent via email to SPL Process Team and ER/DL Team on 7/26/2012)
- e. Further discussion about this topic:
 - i. At the time of this meeting, a subsequent discussion was planned for the SPL ER/DL meeting on Aug 1 with several members of FDA.
 - ii. Post meeting note: After the meeting, the SPL team leaders discussed whether further discussion was needed. While the topic is an issue for several companies, the sponsors have received feedback from several areas of FDA. The topic has been addressed now at several SPL team meetings, and there doesn't seem to be any new or conflicting information that requires additional discussion from the team as a whole. We therefore are cancelling this discussion at next week's SPL ER/DL meeting. If needed, sponsors can initiate individual discussions with the DRLS staff.

2. NDC numbers on different layers of packaging – single units of sale within an outer carton.

Discussion:

- i. CBER and CDER have different interpretations of the regulations related to assignment of NDC codes for products that have multiple layers of packaging – each with the same unit dose.
- ii. CBER is requiring that each level of packaging has a different NDC number - even when there is a 1 in 1 product format. .
 - 1. CBER is using a strict interpretation of the bar code rule. CFR 201.25. The bar code rule states that each level of packaging must have a different code
- iii. CDER: Different levels of packaging must have different NDC codes. For 1 in 1 product format - ie single unit of use in an outer protective package), the same NDC code can be used.
- iv. These have been discussed in several previous SPL ER/DL meetings.

3. NDC codes -- Other Related Questions:

Discussion:

- i. What type of submission will be needed to change an NDC code in labeling:
 - Annual reportable regulations state that NDC codes can be updated via an annual reportable change.
- ii. Are we supposed to comply going forward (i.e. New (A)NDA's), or will we be expected to assign a differentiated NDC for all of our products?
 - Assumption: since NDC codes are required for reimbursement, we are assuming that this needs to be implemented for all products.
- iii. If we must assign a differentiated NDC for all approved/existing products, what is the implementation timeframe?
 - Per the CMS letter to Plan D sponsors, CMS is implementing this on September 1, 2012
- iv. Pharmacy Bulk Packages – How does reimbursement happen when multiple patients receive a dose from the same container – eg Parenteral multidose vials? Individual tablets dispensed from the same bottle?
 - The dose is reimbursed as a percentage of the larger trade package.

AOB:

- 4. **Updating Market Start Dates:** Several companies have received communications from Lonnie Smith stating that CMS is requesting that they update their market start dates in the SPL to be more representative of the real market start date of the product/pack. Question: how widespread is this request? why is this necessary at this time?
 - a. Several companies have received the communication.
 - b. These companies are wondering about this because our initial training on this data did not indicated that an exact market start date was important for drug listing. Therefore,

sponsors/manufacturers have used a variety of processes to assign this date – eg actual market start date, approval date, drug listing date, etc. Some pharma updated the market state date for the product whenever a new pack size was added for that product – ie not maintaining the initial market start date of the product.

- c. Speculation: CMS may be requesting this update because they are starting to use the market start/end dates in the SPL to determine reimbursability – ie whether the product is truly on the market.
- d. **Post meeting note:** The NSDE spreadsheet seems to use the following process for determining the market start date:
 - i. For product/packs drug listing prior to June 1, 2009, the market start date is the date included in the SPL for the product.
 - ii. For products/packs drug listed after June 1, 2009, the market start date is the date the package is drug listed.
- e. **Questions:** During and after the meeting, several questions were raised that we'd like to have addressed in a future discussion – potentially to be addressed by a CMS representative:
 - i. Where is CMS pulling the market start date that they are using as a comparison?
 - ii. Approximations on market start date – what is acceptable?
 - 1. The May 14 letter discussed market start dates and dates of service before Sept 1, 2012. If the market start date in the SPL is prior to this date, why is it necessary to update the market start date?
 - 2. Does the market start date have to be exact to the date CMS is using as the comparison – or close.
 - iii. If a sponsor hasn't been contacted to review/modify its market start dates, can a sponsor assume that the market start dates are acceptable? Or
 - iv. In the CMS letter of May 14, 2012, a process was defined for how CMS will manage NDCs when NDCs are listed more than once with different information.
 - 1. Would you please give examples for situations when an NDC code can be listed more than once? See below for one example.
 - 2. For the assignment of the market end date, the CMS states that the earlier market end date should be used. Based on the scenario described below, we think that the later market end date should be used:
 - i. Oral product, individual blister packs (NDC code 1234-5678-01) is packaged within 2 trade packages. Cartons of 50 (1234-5678-50) and cartons of 80 (1234-5678-80).
 - ii. Marketing ends for cartons of 50 on 9/30/2012. Marketing ends of carton of 80 on 12/31/2012.
 - iii. What is the market end date for reimbursement of the individual blister? 9/30 or 12/31/2012? Ie If a request for reimbursement for the single blister pack comes in with a Date of Service (DOS) of 12/15/2012 – will it be reimbursed?

- f. **To be discussed:** We will discuss this topic at the next SPL ER/DL meeting – in particular to determine what questions need to be clarified. Either the SPL leads will coordinate getting a response and/or invite a CMS representative to discuss at a future meeting.
- 5. **NDC codes for components of kits:** We want to combine two different OTC (non-NDA) products in a kit, but still use the individual NDCs and give the kit a new NDC with of course a different product code. Will this work? Is this how others are doing it? (Ben Harpster)
 - a. Multiple participants stated that this is the way that they manage their NDC codes for kits.
 - b. If the parts are sold separately, then the part NDC code can still be used within a kit.
 - c. A kit must have its own product code.

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